COLGATE-PALMOLIVE

JUN 0 5 2014

510(k) Summary

According to the requirements of 21 CFR 807.92, the following information provides sufficient details to understand the basis for determination of substantial equivalence.

The assigned 510(k) Number: K140481

Submission Date: February 20, 2014
510 (k) Notification: Special 510(k) submission

Submitter Information:

Company: Colgate-Palmolive Company
Address: 909 River Road
Piscataway, NJ 08855 USA
Contact: Charles P. Ireland, MBA
Director of Regulatory Affairs, North America
Telephone: (732) 878-7519
Telefax: (732) 878-7135
Email: Charles_Ireland@colpal.com

Date Prepared: June 2, 2014

Device Information:

Establishment Registration number:	2418748
Common Device:	Mouthwash, Oral rinse Colgate® Desensitizing Mouthwash
Classification Name:	Varnish, Cavity; 21 CFR § 872.3260
Classification Product Code:	LBH
Classification Panel:	Dental
Class:	II

Indications for Use:
For the management of sensitive teeth.
Provides relief from painful sensitivity of teeth to cold, heat, acids, sweets, or contact.
Desensitizes teeth for lasting relief.

Reason for the 510(k): This special premarket notification (Special 510(k)) submission is intended to modify the dosage form of our cleared medical device Colgate® Desensitizing Dental Cream (CDDC) from dentifrice to oral rinse. The components for Colgate® Desensitizing Mouthwash (CDMW) are similar to the previously cleared CDDC, and are commonly used in OTC oral care products. There is no change to the intended use of CDMW and it relies on the same fundamental scientific technology to function. The indications are consistent with the indications cleared in the CDDC 510(k).

Predicate Device used to claim substantial equivalence to:
CDMW has the same intended use and utilizes the same technological characteristics of CDDC our cleared predicate device. The components of CDMW have previously been cleared by CDRH in dental devices, including Colgate® Desensitizing Dental Cream (K103461). The technological characteristics of CDMW differ from CDDC but the fundamental scientific technology is the same.

COLGATE-PALMOLIVE

Trade Name:	Colgate® Desensitizing Dental Cream
Owner:	Colgate-Palmolive Company
510(k) number:	K103461
Product Code:	LBH

Technological Characteristics:
The general components, intended use and application of Colgate® Desensitizing Mouthwash (CDMW) are substantially equivalent to our predicate device CDDC. Open dentin tubules allow the fluid within to transmit external stimuli to the nerves within the dentin pulp and to trigger a pain response, resulting in dentin hypersensitivity. The components of CDMW physically form a thin film that acts like a seal, thereby physically restricting fluid movement through the dentin tubules and preventing external stimuli from triggering a pain response. This physical mechanism of action is responsible for the product's ability to achieve its intended purpose.

Performance Data:
Hydraulic conductance in-vitro study shows that Colgate® Desensitizing Mouthwash (referred to as Colgate® Sensitive Pro-Relief Mouthwash in the report) block dentinal fluid flow by forming a thin film that acts like a seal resulting in the reduction of fluid flow ultimately associated with decrease dentinal hypersensitivity.

The conclusions drawn from the performance testing are that the device is safe and as effective as the predicate device. Furthermore, the device performs its intended use as well as the cleared predicate device and complies with several ISO standards.

Performance Standards:
CDMW complies with the following ISO standards:

- ISO 16408:2004, Dentistry- Oral hygiene products-Oral rinses, 2004.
- ISO 10993-1:2003 (E), Biological evaluation of medical devices – Part 1 Evaluation and testing within a risk management process, 2009.
- ISO 7405: 2008 (E), Dentistry - Evaluation of biocompatibility of medical devices used in dentistry, 2008.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 5, 2014

Colgate-Palmolive Company
Mr. Charles Ireland, MBA
Director, Regulatory Affairs, North America
909 River Road, Post Office Box 1343
Piscataway, NJ 08855

Re: K140481
Trade/Device Name: Colgate Desensitizing Mouth Wash
Regulation Number: 21 CFR 872.3260
Regulation Name: Cavity Varnish
Regulatory Class: II
Product Code: LBH
Dated: May 21, 2014
Received: May 22, 2014

Dear Mr. Ireland:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith, M.S.
Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140481

Device Name
Colgate® Desensitizing Mouthwash

Indications for Use *(Describe)*
For the management of sensitive teeth.
Provides relief from painful sensitivity of teeth to cold, heat, acids, sweets, or contact.
Desensitizes teeth for lasting relief

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Sheena A. Green -S
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